



DIGITAL ACCESS TO SCHOLARSHIP AT HARVARD

Evidence-Based Guidelines and Their Influence on the Standard of Care

The Harvard community has made this article openly available.
[Please share](#) how this access benefits you. Your story matters.

Citation	ChingPing Lin, Evidence-Based Guidelines and Their Influence on the Standard of Care (May 2011).
Accessed	February 19, 2015 9:21:04 AM EST
Citable Link	http://nrs.harvard.edu/urn-3:HUL.InstRepos:8965633
Terms of Use	This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA

(Article begins on next page)

EVIDENCE-BASED GUIDELINES AND THEIR INFLUENCE ON THE STANDARD OF CARE

Food and Drug Law

Winter 2011

LL.M. Paper and Course Paper

ChingPing Lin

May 2, 2011

Table of Contents

I. Evidence-based Medicine and Clinical Practice Guidelines.....	3
A. Definitions.....	3
1. Evidence-based Medicine	3
2. Clinical Practice Guidelines.....	4
3. Example	5
B. Origins and Purposes	9
1. Quality Improvement for Reducing Medical-practice Variation.....	9
2. Cost Reduction.....	10
3. Patient Participation	12
C. Concerns.....	13
II. Standard of Care in Medical Malpractice	15
A. Professional Negligence and Custom	15
B. Reasonable Physician Standard.....	18
C. Duty to Stay Abreast	20
III. The Role of Evidence-based Guidelines in Standards of Care	21
A. Guidelines as Standards of Care	21
B. Guidelines as Evidence of Medical Custom.....	24
C. Guidelines as Evidence of Respectable Minorities.....	27
D. Guidelines as Evidence of Reasonable Care or the Duty to Stay Abreast.....	27
IV. Conclusion.....	30

Introduction

Evidence-based medicine and clinical practice guidelines are spontaneous standardization movements initiated by the medical profession with the goal of quality improvement and cost reduction in health care services since 1970s. However, as Timmermans and Berg point out, “evidence-based guidelines also represent the farthest-reaching and most direct attempts to prescribe and preset the actions of health care professionals.”¹ With the dissemination and implementation of guidelines in medical professionals’ clinical practices, how courts interpret such standards in malpractice litigations would be vital to the regulation of medicine and the development of guidelines.

This paper focuses on the influence of evidence-based guidelines on the legal standard of care, and proceeds in four parts. Part I provides a brief introduction of evidence-based guidelines, including its origin, purposes and related concerns, and uses ACOG guideline as a example. Part II briefly describes two standards of care used in medical malpractice cases—medical custom and reasonable physician standard, along with the duty to stay abreast. Part III analyses the possible influence that guidelines have on different legal standards of care, and shows the challenges that courts may encounter when applying a medical standard to determine legal standard of care. Part IV presents my observations and suggestions for court’s future use of evidence-based guidelines.

¹ STEFAM TIMMERMANS & MARC BERG, THE GOLD STANDARD: THE CHALLENGE OF EVIDENCE-BASED MEDICINE AND STANDARDIZATION IN HEALTH CARE 14 (2003).

I. Evidence-based Medicine and Clinical Practice Guidelines

A. Definitions

1. Evidence-based Medicine

Evidence-based medicine (EBM) is a recent standardization movement in the medical profession that focuses on “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”² The growing body of scientific medical research and advances in information technology since the 1990s contributes to the accumulation of “current best evidence,” which refers to the data produced by strictly controlled medical research, such as randomized, reproducible, and double blind clinical trials.³ As a result, medical knowledge nowadays has a stronger basis in scientific evidence than in the past, when a great deal of medical practice was based on individual physicians’ experience or consensus.⁴

Aiming at quality improvement and cost reduction, EBM promotes a decision-making process that relies on the use of current best evidence with physicians’ clinical expertise and patients’ unique values and circumstances.⁵ With the assistance of such data, a

² David L. Sackett et al., *Evidence-based Medicine: What It Is and What It Isn't*, 312 BRIT. MED. J. 71, 71 (1996).

³ SHARON E. STRAUS ET AL. EVIDENCE-BASED MEDICINE: HOW TO PRACTICE AND TEACH EBM 7-8, 31-35 (3rd ed. 2005).

⁴ The term ‘evidence-based medicine’ was coined in 1992 by a group led by Gordon Guyatt at McMaster University, and was often in comparison with “consensus-based or experience-based medicine.” See Evidence-based Medicine Working Group, *Evidence-based Medicine: A New Approach to Teaching the Practice of Medicine*, 268 JAMA 2420-5 (1992).

⁵ See STRAUS ET AL. *supra* note 3, at 3-4. A standard EBM thinking process consists of a five-step process: (1) converting the need for information (about prevention, diagnosis, prognosis therapy, causation, etc.) into an answerable question, (2) tracking down the best evidence through references to the medical literature, (3) critically appraising evidence for its validity (proximity to the truth), impact (size of the effect), and applicability (usefulness in clinical practice), (4) integrating critical appraisal with clinical

physician is better equipped with the scientific-based knowledge to provide credible diagnoses and prognoses, as well as to better inform patients of the benefits and risks of treatments or alternatives.

2. Clinical Practice Guidelines

Clinical practice guidelines (CPGs), also referred to as practice parameters and clinical pathways, are the most common form of practicing evidence-based medicine. The U.S. Institute of Medicine defines ‘clinical practice guidelines’ as “the consensus statements that have been systematically developed to assist practitioners and patients in making appropriate healthcare decisions for specific clinical circumstance.”⁶ With the tremendous volume of medical journals, research reports, and case studies published at a surprising rate every year, it is not practical to expect a clinician to conduct an evidence-oriented search for relevant research prior to every occasion when he or she must render a medical decision.⁷ As a result, there is a need for a simpler and easier approach to practicing EBM, and this fact helps explain the creation of evidence-based clinical practice guidelines.⁸

A standard process of developing evidence-based guidelines is as follows. First, most guidelines target a specific clinical question, for example, how and when to order

expertise and with patients’ unique biology, values, and circumstances, and (5) applying the results to the patient and evaluating effectiveness and efficiency for future improvements.

⁶ Marilyn J. Field & Kathleen N. Lohr eds., *Guidelines for Clinical Practice: From Development to Use*, 27 INST. OF MED (1992); BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 179 (6th ed. 2008). (Defining ‘guidelines’ further as “standardized specifications for using a procedure or managing a particular clinical problem”)

⁷ For example, a search using the keywords “evidence” and “clinical research” in PubMed will yield more than 5,000 results, and this number is continuously on the rise. See Fig. 1, Jeffrey A. Claridge & Timothy C. Fabian, *History and Development of Evidence-based Medicine*, 29 World J. Surg. 547, 547-48 (2005).

⁸ Arnold J. Rosoff, *Evidence-based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26, No.2 Journal of Health Politics, Policy and Law 327, 328 (2001).

screening tests, how and when to perform a surgery, or how long a patient should remain hospitalized for post-operative care.⁹ With the given question in mind, a panel of medical experts will conduct a systemic review of current medical literature or meta-analyses of statistical data related to the issue, and will then propose a set of recommendations in response to the question. With the help of the recommendations, physicians will be better able to render an evidence-based decision. Moreover, to further facilitate physicians to choose and apply appropriate guidelines, the scope of data reviewed and the methodology used will be disclosed, along with the rating of recommendation, which is made according to the strength of recommendations (level A to C) and the quality of scientific evidence supporting such recommendations (level I to III).¹⁰ Therefore, guidelines work as a clear roadmap for a physician to efficiently and effectively practice evidence-based medicine in the case at hand.

3. Example: ACOG guideline

Today, there are currently over 6,000 evidence-based CPGs, if calculated by topic, that have been written by more than 270 professional societies listed in the United States

⁹ Stefan Timmermans & Aaron Mauck, *The Promises and Pitfalls of Evidence-based Medicine* 24, no.1 Health Affairs 18, 18-19 (2005).

¹⁰ For the guidelines collected in National Guideline Clearinghouse (NGC), there will be a unified rating scheme for the strength of evidence and recommendations as follows:

For Grades of Evidence: (I-III)

I: Evidence obtained from at least one properly designed randomized controlled trial

II-1: Evidence obtained from well-designed controlled trials without randomization

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.

III: Opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations (A-C)

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

National Guideline Clearinghouse (NGC).¹¹ To provide a better illustration of an evidence-based guideline, consider the example below, which is an excerpt of a guideline entitled “Vaginal Birth After Previous Cesarean Delivery,” published by the American College of Obstetricians and Gynecologists (ACOG) in 2010.¹² ACOG conducted literature research by referencing the MEDLINE database, the Cochrane Library, and ACOG’s own internal resources to review relevant articles published between January 1985 and February 2010, and made the following recommendation:

Major Recommendations:

The following recommendations are based on good and consistent scientific evidence (Level A):

- Most women with one previous cesarean delivery with a low transverse incision are candidates for and should be counseled about vaginal birth after cesarean delivery (VBAC) and offered a trial of labor after previous cesarean delivery (TOLAC).
- Epidural anesthesia for labor may be used as part of TOLAC.
- Misoprostol should not be used for third semester cervical ripening or labor induction in patients who have had a cesarean delivery or major uterine surgery.

¹¹ The National Guideline Clearinghouse (NGC) is a publicly available database of evidence-based clinical practice guidelines that provides Internet users with free online access to guidelines at <http://www.guideline.gov>.

The NGC is produced by the Agency for Healthcare Research and Quality (AHRQ, formerly the Agency for Health Care Policy and Research [AHCPR]), in partnership with the American Medical Association (AMA) and the American Association of Health Plans (AAHP) Foundation, with the mission to provide physicians and other health professionals, health care providers, health plans, integrated delivery systems, purchasers, and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation, and use. The AHCPR was active in developing practice guidelines until 1999, when it evolved into its current relatively passive role of coordination and the administration of the NCC because criticism of those guidelines rested largely on cost concerns. See 42 U.S.C. section 299b-1(a)(1994); <http://www.ahrq.gov/> ; <http://www.guideline.gov/browse/by-topic.aspx>

¹²American College of Obstetricians and Gynecologists (ACOG), *Vaginal birth after previous cesarean delivery*, Washington (DC): American College of Obstetricians and Gynecologists (ACOG), 2010 Aug. 14 (ACOG practice bulletin; no. 115) Available at: <http://www.guideline.gov/content.aspx?id=23853>

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Women with two previous low transverse cesarean deliveries may be considered candidates for TOLAC.
- Women with one previous cesarean delivery with a low transverse incision, who are otherwise appropriate candidates for twin vaginal delivery, may be considered candidates for TOLAC.
- External cephalic version for breech presentation is not contraindicated in women with a prior low transverse uterine incision who are at low risk for adverse maternal or neonatal outcomes from external cephalic version and TOLAC.
- Those at high risk for complications (e.g., those with previous classical or T-incision, prior uterine rupture, or extensive transfundal uterine surgery) and those in whom vaginal delivery is otherwise contraindicated (e.g., those with placenta previa) are not generally candidates for planned TOLAC.
- Induction of labor for maternal or fetal indications remains an option in women undergoing TOLAC.
- TOLAC is not contraindicated for women with previous cesarean delivery with an unknown uterine scar type unless there is a high clinical suspicion of a previous classical uterine incision.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- A trial of labor after previous cesarean delivery should be undertaken at facilities capable of emergency deliveries. Because of the risks associated with TOLAC and that uterine rupture and other complications may be unpredictable, the College recommends that TOLAC be undertaken in facilities with staff immediately available to provide emergency care. When resources for immediate cesarean delivery are not available, the College recommends that health care providers and patients considering TOLAC discuss the hospital's resources and availability of obstetric, pediatric, anesthetic, and operating room staffs. Respect for patient autonomy supports that patients should be allowed to accept increased levels of risk; however, patients should be clearly informed of such potential

increase in risk and management alternatives.

- After counseling, the ultimate decision to undergo TOLAC or a repeat cesarean delivery should be made by the patient in consultation with her health care provider. The potential risks and benefits of both TOLAC and elective repeat cesarean delivery should be discussed. Documentation of counseling and the management plan should be included in the medical record.

It is apparent that this set of guidelines targets a patient group—women who have had a cesarean delivery—and recommends the desirable choice of delivery under specified circumstances. There are 3 levels of the strength of the recommendation. The level A recommendation is based on good and consistent scientific evidence, and the strength of the recommendation find expression in words such as “should ” or “should not.” For example, Misoprostol “should not be used” a certain type of patients. The level B recommendations are based on limited or inconsistent scientific evidence, and the expression used is more flexible such as “may be considered” candidates, or “not generally the candidates for” a certain treatment.” In contrast, the level C recommendations, which rest primarily on consensus and expert opinion, are the weakest; thus, the corresponding language is notably more subdued than the aforementioned language. Besides, level C recommendations often take non-medical factors into considerations, such as the facilities, staffs, and resources available, with the emphasis on patient participation. By adopting such a scale, the guidelines accommodate a greater variety of circumstances as well as allow a physician to maintain discretion while applying the guidelines to individual cases.

B. Origins and Purposes

1. Quality Improvement for Reducing Medical-practice Variation

Evidence based guidelines were developed as a response to the problem of medical-practice variation, which came to the public's attention in the 1980s after the publication of a study conducted by John Wennberg.¹³ Wennberg's research shows strikingly high geographical variations in treatment approaches, the length of in-hospital stays in intensive-care units, and preference-sensitive care,¹⁴ which were reflections chiefly of physicians' preferences and could be traced back to the lack of communication between doctors and patients and patients' subordination to a physician's opinion.¹⁵ Such variation, caused concerns about the quality of medical services, and, as Mello argued, contributed to escalating health costs since the 1970s.¹⁶¹⁷ Even today, variation in clinical practices still ranks as the third major concern of the healthcare industry in the United States, while rising healthcare costs and unequal access to healthcare rank as the first and the second.¹⁸

The recommendations that evidence-based guidelines provide help preventing random

¹³ John E. Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, 3 Health Affairs 6, 9 (1984).

¹⁴ Id. (Preference-sensitive care is treatment such as discretionary surgeries for which there are two or more valid treatment alternatives, and the choice of treatment involves tradeoffs that should be based on a patient's preference. Wennberg found that variation in elective surgeries is strikingly high: for example, surgeons in adjoining counties in Florida may operate at very different levels for the same condition and patient.)

¹⁵ John E. Wennberg, *Variation in Use of Medicare Services Among Regions and Selected Academic Medical Centers: Is More Better?*, 874 Commonwealth Fund Pub.4, 4 (2005).

¹⁶ PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 335, 379 (1982). (Between 1950 and 1970, national healthcare expenditure grew from \$12.7 billion to \$71.6 billion (up from 4.5 to 7.3 percent of GNP), and medical care became one of the nation's largest industries.)

¹⁷ Michelle M. Mello, *Of Sword and Shields: The Role of Clinical Practice Guidelines In Medical Malpractice Litigation*, 149 U. Pa. L. Rev. 645, 649-5 (2001).

¹⁸ Timmermans & Mauch, *supra* note 9, at 19.

errors and reducing the variations that have not been verified by science, which is a natural outgrowth of the standardization movement.¹⁹ The value of standardization has long been recognized in modern times as one of the best methods for ensuring the reliability of products and containment of costs.²⁰ In the medical profession, the idea of standardization has been embodied in the standardization of medical education and unified licensing systems, which help to ensure the quality of prospective physicians. Now through evidence-based guidelines, standardization improves the quality of medical decisions.²¹ For example, after the adoption of a clopidogrel-management CPG at the California Pacific Medical Center, the preoperative exposure to clopidogrel dropped from 39% to 6.3%, following a remarkable reduction in chest tube output, blood product use, and bleeding complications.²² For another example, according to research conducted by Texas Children's Hospital in 2009, after the implementation of evidence-based guidelines regarding the treatment of acute chest syndrome (ACS) in children with sickle cell disease (SCD), the average length of stay decreased from 5.8 days to 4.1 days, the patients' average clinical respiratory score improved by 44.5%, and the average cost per admission decreased from \$30,359 to \$22,368.²³

2. Cost Reduction

Cost reduction is another direct benefit produced by standardization, and is at least as

¹⁹ Lynn Etheredge, *Perspective: The Need for Evidence-based Health Policy to Address Health Care*, w3 Health Affairs 366 (2003)

²⁰ Simon C mathews & Peter J. Pronovost, *Physician Autonomy and Informed Decision Making: Finding the Balance for Patient Safety and Quality*, 300 JAMA 2913, 2914 (2008). (Standardization is among the best methods available to improve quality and reduce cost of care)

²¹ TIMMERMANS & BERG, *supra* note 1, at 14.

²² Ley SJ, *Quality Care Outcomes in Cardiac Surgery: the Role of Evidence-based Practice*, 12(4), AACN Clinical Issues, 606-617 (2001).

²³ Crabtree EA et al., *Improving Care for Children with Sickle Cell Disease/Acute Chest Syndrome*, 127(2) Pediatrics 480, 480-488 (2011).

important as quality improvement, particularly insofar as the government has vowed to deal with rising healthcare costs.²⁴ Evidence-based guidelines have helped reduce healthcare costs in several ways. First, the guidelines have helped reduce defensive medicine.²⁵ According to research conducted by Mello and her colleagues on the national cost of the medical liability system in 2008, the cost of defensive medicine was as high as U.S. \$45.59 billion.²⁶ The practice of defensive medicine has resulted largely from doctors' fear of medical malpractice lawsuits.²⁷ Evidence-based guidelines provide implicit assurance to physicians that, whenever following a specific guideline, they are making desirable medical judgments, thus lessening the physicians' worries of medical malpractice litigation. Second, facing the endless demand for better and more healthcare services in the population, a great number of guidelines also rest on cost-benefit analysis methodology in order to prompt physicians to make a cost-effective choice with limited resources.²⁸ As Tucker puts it, clinical-practice guidelines constitute "a powerful tool to deliver a limited amount of healthcare to the greatest number of people in the most effective way."²⁹

²⁴ FURROW ET AL., *supra* note 6, at 349.

²⁵ The U.S. Congress Office of Technology Assessment (OTA) proposed the most commonly used definition of 'defensive medicine', which conceptualizes defensive medicine as occurring "when doctors order tests, procedures, or visits, or avoid certain high-risk patients or procedures, primarily (but not solely) because of concern about malpractice liability."

²⁶ See, Michelle M. Mello, Amitabh Chandra, Atul A. Gawande and David M. Studdert, *National Costs of the Medical Liability System*, 29 No. 9 Health Affairs, 1569-1577 (2010).

²⁷ See T BAKER, *THE MEDICAL MALPRACTICE MYTH* (2005); and Taschi Karen-Paz, *Liability Regimes, Reputation Loss, and Defensive Medicine*, 18 MEDLREV 363, 375-376 (2010). But, see David Klingman et al., *Measuring Defensive Medicine Using Clinical Scenario Surveys*, 21 Journal of Health Politics, Policy and Law 185, 201-205 (1996) (Klingman and his colleagues argue that defensive medicine is motivated by aggressive clinical choices rather than the fear of malpractice liability.)

²⁸ Rosoff, *supra* note 8, at 337-38; Mello, *supra* note 17, at 651-52.

²⁹ John Tucker, *A Novel Approach to Determining Best Medical Practices: Looking at the Evidence*, 10 Hous. J. Health L. & Policy 147, 155 (2009).

3. Patient Participation

To improve patient-centered medical practices is another important goal of evidence-based guidelines.³⁰ For example, in the previously mentioned ACOG guidelines, patients' participation is specified particularly in the recommendation that "patients should be clearly informed of such potential increase in risk and management alternatives." Research also shows that, when better informed about the risks, benefits, alternatives and outcomes, patients not only better understand the matter at hand when making a decision, but also have greater confidence in the decision.³¹ Guidelines facilitate the interaction between patients and physicians, which is a win-win situation that we are more than happy to see.

Last but not least, evidence-based guidelines work as a strong defense of self-regulation in the medical profession, which has long been entrusted with the power and privilege of self-monitoring.³² By adopting evidence-based guidelines, the medical profession has not only consolidated the bond between medicine and science, but also displayed the profession's spontaneous efforts to keep its promise of pursuing improvements in the quality of society.³³

³⁰ See STRAUS ET AL., *Supra* note 3, at 1. (EBM encourages physicians to emphasize patient value and consider patients' unique preferences, expectations, and concerns when making a clinical decision.)

³¹ O'Connor AM, Bennett CL, Stacey D, Barry M, Col NF, Eden KB, et al., *Decision Aids for People Facing Health Treatment or Screening Decisions*, 3 Cochrane Database System Review143 (2009).

³² For a thorough introduction of the origins and development of the self-regulation of the medical profession between 1850-1930, see STARR, *supra* note 16, at 79-144.

³³ Michelle M. Mello, *Using Statistical Evidence to Prove the Malpractice Standard of Care: Bridging Legal, Clinical, and Statistical Thinking*, 37 Wake Forest L. Rev. 821, 822 (2002); Angel Campell & Kathleen Cranley Glass, *The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research*, 46 McGill Law Journal 473, 476 (2001) (Constructing scientifically optimal CPGs is necessary for the credibility of medicine.); Timmermans & Mauch, *supra* note 9, at 21.

C. Concerns

There are many concerns—both within the medical community and outside it—associated with the widespread presence of evidence-based guidelines. First of all, even though the guidelines have achieved great success in medical education and clinical application, the medical profession has mixed feelings about them because of their potential threat to clinicians’ autonomy.³⁴ Opponents criticize that guidelines bring about “cookbook medicine” or “checklist medicine,” which deprives doctors of the critical discretionary power that is essential for them as professionals because the rigid application of guidelines ignores the uncertainty in medical practice and depreciates the value of clinical judgment.³⁵ Furthermore, this infringement upon professional autonomy is unprecedented because it dictates the content and the details of day-to-day decisions rather than set the minimum competence threshold, as licensing and board-certification systems have done.”³⁶

Second, there is still no single authority on practice guidelines, and this vacuum translates into the problems of multiple guideline issuers and conflicting guidelines.³⁷ Although professional associations and societies have issued a great majority of the evidence-based

³⁴ Rosoff, *supra* note 8, at 329. (Some parts of the medical community view EBM as a mixed blessing. Some parts of the medical community worry that the spread of CPGs have the potential to turn doctors into automatons and lower the quality of health care by subordinating and subverting professional skills and judgment.)

³⁵ RITZER G. THE MCDONALDIZATION OF SOCIETY: AN INVESTIGATION INTO THE CHANGING CHARACTER OF CONTEMPORARY SOCIAL LIFE, (1992); B.G.Charlton, *Restoring the Balance: Evidence-based Medicine Put in Its Place*, 3 no.2 *Journal of Evaluation in Clinical Practice* 87-98 (1997); TIMMERMANS & BERG, *supra* note 1, at 19.

³⁶ *Supra* note 1.

³⁷ The Agency for Health Care Policy and Research (AHCPR) was reauthorized under the Healthcare Research and Quality Act of 1999, and changed its name to the Agency for Healthcare Research and Quality (AHRQ). The Act redefined AHCPR’s role from that of an active creator and regulator of evidence-based guidelines to that of a less active actor in the funding of research and the maintaining of the “National Guideline Clearinghouse” database, See, AHRQ Reauthorization Fact Sheet, <http://www.ahrq.gov/about/ahrqfact.htm>; <http://guideline.gov/>; Also see *supra* note 11.

guidelines, managed-care organizations (MCOs) and private insurers have also issued guidelines with the predominant purpose of improving the effective use of medical resources.³⁸ Because these guidelines are often held as the standard for reimbursement, utilization review or physician profiling purposes, in practice, they have had a stronger effect on physician compliance than the guidelines “suggested” by professional associations.³⁹ (This problem involves a broader debate about whether it is desirable for physicians to implement cost-oriented choices, a topic that is beyond the scope of this paper.⁴⁰) Furthermore, concerns about potential conflicts of interests resulted from funding sources are raised to the guideline generators, including professional associations and societies. In 2010, the National Guideline Clearinghouse/National Quality Measures Clearinghouse (NGC/NQMC) Core Editorial Board reviewed the current guidelines published in NGC, and found out that only 60% of the guidelines have statements about the presence or absence of potential conflicts of interest.⁴¹ The problem of multiple issuers or cost-oriented guidelines might contribute to another problem of inconsistent or

³⁸ Rosoff, *supra* note 8, at 337-38; Mello, *supra* note 17, at 651-52.

³⁹ Jamie Lynn Armitage, *Case Note: Pegram v. Herdrich: HMO Physicians as Fiduciaries*, 5 DEPAUL J. HEALTH CARE L. 341, 360 (2002) ; Mello, *supra* note 17, at 651-652 (Both conducted by the third party payers, utilization review is the evaluation to review physician’s treatment order in order to determine whether such care will be reimbursed, and physician profiling is the analysis of a physician’s practice pattern to see whether his/her practice is cost-efficient, which might influence physician’s participation in a HMO); Timmermans & Mauch, *supra* note 9, at 21. (Third party guideline might bring result in the further “deprofessionalization” of medicine.”)

⁴⁰ FURROW ET AL., *supra* note 6, at 199. (The medical profession has long won great respect from patients and society in general because there is a common conception that doctors engage an honorable work by dedicating their expertise exclusively to patients and are free from significant conflicts of interest involving.) However, a cost-oriented set of guidelines would entail more than purely patient interests, thus creating potential conflicts of interest in physicians’ role as an advocate for patients and physicians’ role as an advocate for public cost-control policy.

⁴¹ NGC/NQMC Editorial Board: Richard C. Hermann et al., *Expert Commentaries: Promoting Transparent and Actionable Clinical Practice Guidelines: Viewpoint from the National Guideline Clearinghouse/National Quality Measures Clearinghouse (NGC/NQMC)*, National Guideline Clearing House (Dec 20, 2010), <http://www.guideline.gov/expert/expert-commentary.aspx?id=24556>

conflicting guidelines, which further creates more confusion and difficulty in guideline application.⁴²

Third, probably the most controversial and influential issue of evidence-based guidelines is whether the guidelines should serve as the legal standard of care in medical malpractice cases. This issue involves an interdisciplinary dialogue between law and medicine, and in the following pages, I will clarify the purposes, standards, and influences of the medical-malpractice system before identifying the guidelines' important roles.

II. Standard of Care in Medical Malpractice

A. Professional Negligence and Custom

Among the four tenets required to establish a tort claim, namely, duty, breach, causation, and injury, the issue of breaching a standard of care is usually the threshold question in medical malpractice cases.⁴³ In most jurisdictions, when determining the standard of care for professionals, the courts give custom the conclusive weight. As a result, if a defendant physician proves that what he or she has done is in consistent with the generally recognized and accepted practice in the medical profession, the court will find no breach

⁴² Rosoff, *supra* note 8, 332-336. (Rosoff suggests that the problem of conflicting CPGs will only shift the current battle of expert testimony in courts from a "battle of experts" into a "battle of super experts," and allows courts to decide which guideline-generating organization is entitled to more respect).

⁴³ Troyen A. Brennan, *Tort Law as It Applies to Medical Malpractice Litigation*, LEGAL ASPECTS OF MEDICINE: INCLUDING CARDIOLOGY, PULMONARY MEDICINE, AND CRITICAL CARE MEDICINE 23 (J.R. Vevaina et al. eds., 1989)

in the duty of care, and jury is prohibited from rejecting such practice as improper.⁴⁴ This standard is often referred to as “customary care” or the “professional community standard,” in contrast to the “reasonableness standard” in ordinary negligence cases.⁴⁵ For example, in *Johnson v. Riverside Anesthesia Associates, P.C.*⁴⁶, the Supreme Court of Georgia rules that:

“It is axiomatic that in order to establish medical malpractice, “the evidence presented by the patient must show a violation of the degree of care and skill required of a physician. Such standard of care is that which, *under similar conditions and like circumstances, is ordinarily employed by the medical profession generally.*” Thus, in medical malpractice actions, “[t]he applicable standard of care is that employed by the medical profession generally and not what one individual doctor thought was advisable and would have done under the circumstances.””

There are several reasons supporting the judicial deference to the collective wisdom of the medical profession. First, because a medical decision requires expertise, knowledge, and experience that are generally beyond the layperson’s abilities, it is difficult for juries to decide what a reasonable physician should have done under circumstances similar to

⁴⁴ Mello, *supra* note 17, at 656, 657. (In tort law generally, a defendant’s compliance with custom is not dispositive if there is a negligence claim. Medical malpractice law, however, has evolved somewhat differently); FURROW ET AL, *supra* note 6, at 361; Clarence Morris, *Custom and Negligence*, 42 COLUM. L. REV. 1147, 1147, 1158 (1942).

⁴⁵ The reasonableness standard requires “the degree of care that a reasonable person of ordinary prudence would have exercised under the same or similar circumstances.” See RESTATEMENT (SECOND) OF TORTS § 283 (1965); For a detailed introduction of professional custom standard, see JOHN C. GOLDBERG, *TORT LAW: RESPONSIBILITIES AND REDRESS* 171-188 (2nd ed. 2008).

⁴⁶ 275 Ga. 240, 563 S.E.2d 431 (Ga., 2002)

those that the juries are considering.⁴⁷ Second, the characteristics of professionalism and disinterestedness arise, at least in perceptions, from the patient-physician relationship; thereby distinguishing medical practitioners from profit seekers, and thus justifying assertions that the medical profession deserves to regulate itself.⁴⁸

One thing worth mentioning is that the level of care that courts require a given doctor to exhibit need not be the highest possible level, but should reflect the same level of care, skill, and diligence that is ordinarily possessed and exercised, under similar circumstances, by the typical member of the doctor's profession. For example, in *Pittman v. Stevens*⁴⁹ the court rules that the duty of care is

“A physician...is required to provide his patients with that same degree of care, skill and diligence which would be provided by *a minimally competent, reasonably prudent physician* in the same general field of practice, under the same or similar circumstances, and who has available to him the same general facilities, resources and options.”

As a result, the determination of medical custom is a question of fact, and juries depend heavily on the testimony of medical experts to render decisions. An expert is supposed to testify about what others in the profession commonly would do in such a situation rather

⁴⁷ Supra note 45.

⁴⁸ Tim Cramm, Arthur J. Hartz, and Michael D. Green, *Ascertaining Customary Care in Malpractice Cases: Asking those who know*, 37 Wake Forest Law Review 699, 702 (2002).

⁴⁹ *Pittman v. Stevens*, 364 S.C. 337 (2005).

than what he or she thinks should have been done.⁵⁰ In addition, a majority of experts will refer to clinical literature, research findings, and the Physicians Desk Reference (PDR) to support his or her testimony,⁵¹ and some courts even make it a requirement.⁵²

B. Reasonable Physician Standard

Although customary practice remains the legal standard for malpractice in many states, almost half of the states have adopted an objective “reasonable physician standard” instead.⁵³ Under this standard, a physician should possess and exercise the skill and care that a reasonable physician under the same or similar circumstances would possess and exercise, and such inquiry becomes a question of law instead of a question of fact.⁵⁴ Therefore, the reasonable physician standard gives judges and juries more latitude in reviewing customs and relevant medical knowledge when deciding what the applicable standard should be.⁵⁵

This shift in standards stems mainly from (1) the public’s general distrust of letting a profession set its own standards and (2) problems associated with expert testimony. For one thing, plaintiffs often have difficulty obtaining expert testimony owing to the “conspiracy of silence,” according to which few experts in a given field would be willing

⁵⁰ Rosoff, *supra* note 8, at 332; *Johnson v. Riverside Anesthesia Associates, P.C.*, 275 Ga. 240, 563 S.E.2d 431 (Ga., 2002)

⁵¹ *Travers v. District of Columbia*, 672 A.2d (D.C.App. 1996)

⁵² FURROW ET AL., *supra* note 6, at 339-40

⁵³ Michael D. Greenberg, *Medical Malpractice and New Devices: Defining an Elusive Standard of Care*, 19 Health Matrix 423, 428 (2009); Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 187-88 (2000).

⁵⁴ *See Ande v. Rock*, 256 Wis. 2d 365, 377, 647 N.W. 2d 265, 271 (Ct. App. 2002).

⁵⁵ Greenberg, *supra* note 53, at 429.

to testify against their peers.⁵⁶ For another thing, the reliance on expert testimony to ascertain medical customs is problematic because an expert, even as a practitioner, often has no actual knowledge about how the majority of doctors practice medicine.⁵⁷ Most of these experts rely on their personal experience or theoretical assumptions about what is reasonable or what they, as experts, would have done under the same circumstances.⁵⁸ However, the greatest concern about reasonable physician standard is that it might migrate toward ideal care and, thus, might place an impractical and unreasonable burden on physicians. The most representative case is the 1974 *Helling v. Carey*,⁵⁹ in which the Washington Supreme Court imposed its own risk-benefit judgment and held that a customary practice did not meet the reasonable care standard. However, the decision in this case came under considerable criticism for being radical and excessively aggressive. Indeed, Washington courts are considered atypical in comparison with most states.⁶⁰

To conclude, the standard of care in medical malpractice cases is still a diversified and unsettled issue among states. Although the standard of care has evolved from “customary care” to a “reasonable physician” standard, most courts are still unwilling to allow a plaintiff to attack a customary practice with which a defendant physician complied,

⁵⁶ *Largey v. Rothman*, 540 A.2d 504 (N.J. 1988) (The court reasoned that “a professional standard if totally subject to the whim of the physicians in the particular community, and under such review a physician is vested with virtually unlimited discretion...and such standard has created problems for patients trying to find physicians willing to breach the “community of silence” by testifying against fellow colleagues.)

⁵⁷ Cramm et al, *supra* note 48. (Evidence shows that most physicians don’t know how their peers practice medicine. Cramm, Hartz and Green identify three studies illustrating that expert witnesses often lack the ability to empirically identify actual customs. Most expert witnesses determine the standard of care according to what they, themselves, would have done under the same circumstances and assume that customary care is similar.)

⁵⁸ *Id.* at 700.

⁵⁹ *Helling v. Carey*, 83 Wash. 2d 514 (1974).

⁶⁰ Mello, *supra* note 17, at 658-60.

except under rare circumstances.⁶¹ Several scholars have emphasized the value of medical custom: for instance, Professor Richard Lempert argued that customary standard can work as a relief valve, especially when customary care lags behind reasonable care.⁶²

C. Duty to Stay Abreast

Besides the duty to possess knowledge and skill and to exercise care according to the standard of care, there is the duty to stay abreast. With the rapid advances in medical technology and knowledge, it is reasonable for courts to expect the standard of care to progress in accordance with these other advances. Under this duty, a physician is required to be aware of evolving practices in medical care, and to make appropriate use of new scientific knowledge in medicine as it emerges.⁶³

However, although has evolved in the field of judicial decision-making, the duty to stay abreast remains largely undefined. As Williams points out, “The current doctrine does little to explain to a physician what he/she must to do to keep up because courts define the duty in vague terms and there is little case law to inform physicians of what exactly it means to ‘stay abreast.’”⁶⁴

⁶¹ *Burton v. Brooklyn Doctor Hospital*, 88 A.D.2d 217, 452 N.Y.S 2d 875 (1982).

⁶² Richard Lempert, *Following the Man on the Clapham Omnibus: Social Science Evidence in Malpractice Litigation*, 37 Wake Forest Rev. 903 (2002), see FURROW ET AL., supra note 6, at 337-38.

⁶³ In *Klisch v. Meritcare Medical Group, Inc.*, 134 F.3d 1356 (1998), the 8th Circuit Court held that juries should consider the state of medical technology at the time of the given allegedly negligent medical event in order to determine the appropriateness of that event. See FURROW ET AL., supra note 6, at 338.

⁶⁴ Carter L. Williams, *Evidence-based Medicine in the Law Beyond Clinical Practice Guidelines: What Effect Will EBM Have on the Standard of Care?*, 61 Wash. & Lee L. Rev. 479, 513-14 (2004).

III. The Role of Evidence-based Guidelines in Standards of Care

The use of evidence-based guidelines in determining standards of care is tempting for courts as well as for litigants. For courts, the most authoritative standards derive not from costly expert testimony but from evidence-based guidelines—proposed by the medical profession itself and based supposedly on solid scientific evidence and expert consensus. Patient plaintiffs look with a suspicious eye on a physician’s deviation from explicit guidelines, and thus an inculpatory neglect of guidelines can simplify the plaintiffs’ task of proving other forms of negligence.⁶⁵ Defendant physicians would likely find that their compliance with guidelines could work as a strong defense against accusations of negligence, thus minimizing—if not eliminating—the fear many physicians have of litigation, and making the practice of medicine more predictable. However, such reasoning might be too straightforward and ideal.

A. Guidelines as Standards of Care

Argument could be made that evidence-based guidelines should bear conclusive weight regarding standard of care; however, neither the medical profession nor courts welcome such ideas. The medical profession strongly opposes the idea, arguing that evidence-

⁶⁵ See Hyams A. et al., *Medical Practice Guidelines in Malpractice Litigation: an Early Retrospective*, 21 *Journal of Health Politics, Policy and Law* 289-313 (1996). (Studies show that plaintiffs have a more frequent use of CPGs and such uses have a positive correlation to the success rate for plaintiffs in the litigation.)

based guidelines are merely suggestions for better medical practices.⁶⁶ Holding the guidelines up as standards of care and characterizing any departure from these guidelines as an act of negligence not only impose a tremendous burden on physicians but also penalize physicians' efforts, made in good will, to improve on existing practices. Such consequences could have chilling effects that would, so the argument goes, undermine evidence-based guidelines.⁶⁷

In addition, courts are cautious when considering the use of clinical practice guidelines as standards of care.⁶⁸ In *Hinlicky v. Dreyfuss*,⁶⁹ the court explicitly ruled that even though the clinical practice guidelines had been admitted as evidence, they did not constitute—in themselves—standards of care.⁷⁰ The court also refused the argument that the Physicians Desk Reference (PDR) constitutes prima facie evidence of the standard of care, and rules that although PDR could have some significance in identifying a doctor's standard of care, but it could not be determinative. The reasoning that rejects PDR as standard of care could be used to predict courts' attitude toward evidence-based guidelines because PDR is a type of guideline as well. Moreover, a fundamental rationale against such idea might be, a straight application of evidence-based guidelines as a standard of care would

⁶⁶ Rosoff, *supra* note 8, at 331 (In the short runs, the adoption of evidence-based medicine by courts can generate more cost than benefits.)

⁶⁷ Williams, *supra* note 64, at 484.

⁶⁸ FURROW ET AL., *supra* note 6, at 349.

⁶⁹ *Hinlicky v. Dreyfuss* 6 N.Y.3d 636, 816 N.Y.S.2d 908, 848 N.E.2d 1285 (2006)

⁷⁰ The physician defendant argued that he had followed a set of clinical guidelines published in 1996 by the American Heart Association (AHA) in association with the American College of Cardiology (ACC) in determining whether the plaintiff should have a preoperative cardiac evaluation. The trial court admitted the guidelines as evidence under the professional-reliability exception to the rule against hearsay. The Court of Appeals of New York affirmed the decision, ruling that the guideline is not admitted as evidence to establish a standard of care, but to illustrate the defendant's decision-making process.

be a total forfeiture of judicial power, which runs counter to the principle of checks and balances as a way to manage power.

However, there were statutory attempts to permit physicians' exculpatory use of guidelines as affirmative defenses in medical malpractice litigation in states such as Kentucky⁷¹, Florida⁷² and Maine⁷³ in the 1990s. The purposes of these experimental statutes were to reduce the practice of defensive medicine and litigation costs as well as to encourage physicians to use CPGs. As a result, the courts treat physicians' compliance with certain guidelines as prima facie evidence that the physicians had substantially met a standard of care. However, the effect of these statutes was not as expected.⁷⁴ For example, empirical studies show that the Maine statutes (the Maine Project) influenced perhaps only about 3 to 4% of medical practice.⁷⁵ Moreover, because the statutes does not allow plaintiffs' use the of guidelines as prima facie evidence for standard of care, scholars also criticized the statutes as unfairly favoring physicians and as unconstitutional

⁷¹ See Ky. Rev. Stat. Ann section 342.035(8)(b), which states that "any provider of medical services under this chapter who has followed the practice parameters or guidelines developed or adopted pursuant to this subsection shall be presumed to have met the appropriate legal standard of care in medical malpractice cases regardless of any unanticipated complication that may thereafter develop or be discovered."

⁷² See Ash Samanta et al., *The Role of Clinical Practice Guidelines in Medical Negligence Litigations: A Shift from the Bolam Standard?*, 14 Med. L. Rev. 321, 341 (2006). (Florida project allows the compliance with guidelines to constitute an affirmative defense doesn't provide sufficient incentive for physicians to reduce defensive medicine.)

⁷³ See Gordon H. Smith, *A Case Study in Progress: Practice Guidelines and the Affirmative Defense in Maine*, 19 Joint Commission J. on Quality improvement 355, 355-61 (1993). (Maine Project is the statutory experiment that allows guidelines be used as an affirmative defense for physicians who volunteered to follow established CPGs in four specialty areas, anesthesia, emergency medicine, radiology, and obstetrics and gynecology, with the purpose of certainty and reducing defensive medicine.)

⁷⁴ See, Jodi M. Finder, *The Future of Practice Guidelines: Should They Constitute Conclusive Evidence of the Standard of Care?*, 10 Health Matrix 67, 104-106 (2000). (Finder points out three obstacles hindering the Maine Project: (1) the legislation did not preclude the possibility of lengthy litigation, (2) it denied plaintiffs' right to a jury trial and the use of evidence regarding guidelines, and (3) the creation of guidelines might not be reliable.)

⁷⁵ Supra note 64, at 361.

violating patient's right of due process or equal protection of law.⁷⁶ As a result, there is a general consensus about guidelines should not constitute a de facto legal standard that is applied rigidly in every case.⁷⁷

B. Guidelines as Evidence of Medical Custom

Guidelines serve to help standardize physicians' behavior for the betterment of medical practices.⁷⁸ With proper dissemination, such guidelines could integrate themselves into clinical practices and become medical custom. As a result, even when not having a dispositive effect, guidelines could serve as evidence to identify medical custom in courtrooms. However, the biggest problem with this overall assessment of guidelines is that, up to the present, this integration process is far from complete.

Many scholars have pointed out that the disparity between guidelines and current medical practices is the biggest concern regarding the use of guidelines as evidence of customary care. In a widely cited article "Of Sword and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation" in 2001, Mello suggests that a majority of CPGs do not represent the prevailing medical practice, and that "there exists little agreement as to whether CPGs represent a minimum baseline, a not-yet-attained ideal, or a customary practice that lies somewhere between these two extremes."⁷⁹ Her argument still stands true today. In August 2007, the Society of American Gastrointestinal

⁷⁶ Samanta et al., *supra* note 72, at 340-41; Rosoff, *supra* note 8, at 344.

⁷⁷ B. Hurwitz, *How does Evidence Based Guidelines Influence Determination of Medical Negligence?*, 329 B.M.J. 1024 (2004).

⁷⁸ TIMMERMANS & BERG, *supra* note 1, at 85.

⁷⁹ Mello, *supra* note 17, at 680; Cramm et al, *supra* note 48, at 750 (Cramm, Hartz and Green also argue that CPGs constitute an unfit means of determining standards of care because there is uncertainty as to whether they represent medical custom or ideal practice); Finder, *supra* note 74.

Endoscopic Surgeons (SAGES) conducted an electronic survey of its members about their use of SAGES-suggested guidelines, and the survey shows that only 50% of the respondents used the guidelines.⁸⁰ In addition, Timmers and Muack observed that for most of the practitioners, guidelines constituted only an option instead of a true standard and that practitioners' use of these guidelines was widely discretionary, in effect rendering the guidelines inadequate to the task of effectively changing clinical care.⁸¹ As a result, courts should be aware that even though a guideline is generally recognized as a good practice, it might not function as an integrated component of general practice.

Moreover, a great number of cost-oriented guidelines have significantly complicated efforts to standardize care. Even if a cost-oriented guideline has integrated itself into general practice and become medical custom, a departure from such guidelines does not necessarily mean that the physician has substandard care, skills, and diligence. Instead, such a departure at most shows doctors who render decisions that are not cost-efficient. For example, Columbia University conducted an institutional review between 2005-2007 among 1,402 female patients who underwent gynecologic surgery. The results show that 95 % of the patients underwent all of the guideline-recommended preoperative testing, yet 90% of them underwent at least 1 non-indicated preoperative test. Of the tests conducted, about 30% were in accordance with evidence-based guidelines. The research concludes that adherence to evidence-based recommendations for preoperative testing is

⁸⁰ Dimitrios Stefanidis et al., *What is the Utilization of the SAGES Guidelines by Its Members?*, 24 Surg Endosc 3210, 3210-15 (2010).

⁸¹ Timmermans & Mauch, *supra* note 9, at 22-23, 26.

poor, and that such inappropriate preoperative tests led to direct costs of more than \$418,000.⁸²

As we see in this research, departure from a guideline could result in “over-treating” instead of “under-treating.” However, every treatment carries certain inherent risks that are inevitable even when conducted by doctors who exercise their best knowledge and skill. Consider a situation where risk-averse doctors recommend a procedure on the basis of their medical judgment even though the guidelines recommend against the procedure, and despite the doctors’ utmost care, the patients suffer harm from the procedure. One can argue that the physician’s over-treating decision exposes the patient to unnecessary potentially harmful risks for which physicians should be responsible. However, it is also arguable that the doctors should not be held liable for their risk-averse approach simply because it clashes with the guidelines that is reflective of cost-reduction preferences or resource limitations. In this scenario, the doctor may just be fighting for his professional judgment of what is optimal for his/her patient’s benefits against a system-wide decision about what is optimal for most patients, which differs from the scenario of careless doctors that medical malpractice system intends to capture. However, if we uniformly treat earnest departures from guidelines as careless departures from standard of care, doctors would likely be liable for their choices.

⁸² St Clair CM et al., *Adherence to evidence-based guidelines for preoperative testing in women undergoing gynecologic surgery*, 116(3) *Obstet Gynecol* 694-700 (2010).

C. Guidelines as Evidence of Respectable Minorities

Even though a guideline may not faithfully reflect medical custom, it could act as strong evidence for respectable alternative approaches. Recognizing the diversity of treatments and approaches in medicine, the courts have adopted the “respectable minority doctrine” (or the “two schools of thought” doctrine) to allow a physician to choose an accepted alternative treatment that differs from majority practice but is recognized by a considerable number of respected professionals so long as the doctor in question acts not out of negligence but in the best interests of his or her patients.⁸³ An evidence-based guideline lends its credibility and authority to a respectable alternative approach, which has its special value in the cases of new medical devices and treatments. Physicians often are hesitant about adopting new medical devices because the potential departure from customary practice might entail malpractice liability risks.⁸⁴ However, if a newly developed medical device is recognized and accommodated in a evidence-based guideline, courts can be better able to apply the respectable minority doctrine, thereby further encouraging physicians to adopt new devices by reducing liability concerns.

D. Guidelines as Evidence of Reasonable Care or the Duty to Stay Abreast

Medical professionals, courts, and society as a whole share the desire for better medical practice. However, this general consensus does not mean that courts, in determining malpractice liability, must hold medical professionals to every standard to which they hold themselves. Tort liability is a powerful tool in allocating loss and creating

⁸³ FURROW ET AL., *supra* note 6, at 381-384.

⁸⁴ Greenberg, *supra* note 53, at 430.

deterrence to encourage future compliance, but it should be used with great caution. As a matter of fact, courts have long been cautious when using standards of care to evaluate whether there has been wrongdoing by average individuals as well as by professionals; indeed, the requirement is not that such individuals exercise extraordinary skills and care, but that the individuals meet a threshold of minimum competence acceptable to the society.⁸⁵

Courts' use of evidence-based guidelines as evidence to establish reasonable care standards or as the basis of the duty to stay abreast creates concerns similar to those characterizing the argument that courts should not treat these guidelines as standards of care per se in Part A. The chief concern is that the aggressive interpretation of the desirable standard encouraged by guidelines into the legal reasonable care standard could trigger radical changes to current medical practices. Moreover, even when using guidelines only as evidence for standards of care, a court still runs the risk of changing guidelines' aspirational characteristic, which is essential to the guidelines' proper functioning.

The aspirational characteristic of evidence-based guidelines aims at preserving each practitioner's clinical autonomy, mitigating the concerns of cookbook medicine.⁸⁶ The practice of medicine has been referred to as a mix of science and art because the uncertainty is so omnipresent that science alone cannot manage medicine. For example,

⁸⁵ See *Pittman v. Stevens*, supra note 49.

⁸⁶ T. S. Cheah, *The Impact of Clinical Guideline and Clinical Pathways on Medical Practice: Effectiveness and Medico-legal Aspects*, 27 *Annals Acad. Med. Sing.* 533, 536 (1998). (It's a physician's duty and discretion to decide whether a guideline is applicable to the patient at hand.)

the uncertainty caused by each patient's different health conditions and reactions to treatments shows the continuous need for medical professionals to observe and adjust during the course of treatment, and this is mainly accomplished by doctors' experience and professional judgment. As a result, when a guideline is created, it is intended to accommodate such diversity and flexibility, thus functioning more as guidance rather than as a set of mandates. As Eddy points out, the flexibility is inherent in guidelines and is the necessary tradeoff when guiding the decision making in a number of similar cases rather than in a single one.⁸⁷ However, holding a guideline as evidence for standards of care might twist such flexibility and aspiration characteristic, leaving little room for professional judgment.

Furthermore, the evidence use of guidelines tends to deepen the misperception of error-free medicine.⁸⁸ The idea of a standardized process seems to simplify decision-making and makes any departure from the standard more blamable. However, as Gawande observed, "medicine today has become the art of managing extreme complexity—and a test of whether such complexity can, in fact, be humanly mastered."⁸⁹ With the ever-changing pace of scientific advances in medical knowledge and medical products, guidelines at most, work only as the tool that allows doctors to barely keep up with such advances, instead of, to have a complete command of errors. Human beings are not flawless. We are blessed with emotion and reason, and we make mistakes. Guidelines help doctors to reduce mistakes, but it is not the elixir for error-free medicine. However,

⁸⁷ David M. Eddy, *Designing a Practice Policy: Standards, Guidelines, and Options*, 263 JAMA 3077, 3081 (1990).

⁸⁸ For a further discussion of medical errors, see FURROW ET AL., *supra* note 6, at 41-67.

⁸⁹ ATUL GAWANDE, *THE CHECKLIST MANIFESTO: HOW TO GET THINGS RIGHT* 8, 19, (2010)

the use of guidelines could create a stereotype that the practice of medicine is more standardized and simple.

Last but not least, overly demanding standards of care not only invite more costly malpractice litigation but also can undermine a doctor's passion for medicine. Most doctors still believe Hippocrates' famous admonition "first, do no harm," and try to honor this belief in day-to-day practice. However, many doctors lose their passion for medicine after undergoing the traumatizing experience of a malpractice lawsuit. The resulting social pressures and damage to professional image are two key factors contributing to declines in doctors' enthusiasm for their practice.⁹⁰ Guidelines are supposed to elevate healthcare quality as a whole, rather than simply weed out incompetent or negligent professionals. When used aggressively to judge a practitioner's behavior, guidelines could become excessive and can result in unfair allocations of losses imposed by malpractice liability. Last but not least, the most deleterious side effect might be both the value we destroy when we drive practitioners out of practice and when we squander societies' investment in medical professionals.

IV. Conclusion

The main purposes of this paper are to identify and to analyze (1) differences between medical standards and legal standards of care, and (2) the difficulty of integrating the former into the latter. In my opinion, the courts should be cautious while facing the

⁹⁰ Herbert Dicker, JD, and Jeffery D. Robertson, JD, *the Defense of a Malpractice Case*, J.R. Vevaina, R.C. Bone, and E. Kassoff (editors), 15 LEGAL ASPECTS OF MEDICINE: INCLUDING CARDIOLOGY, PULMONARY MEDICINE, AND CRITICAL CARE MEDICINE (1989).

temptation to use evidence-based guidelines as standards of care. On the one hand, even though the development of evidence-based guidelines is widely recognized as desirable and valuable, it is still an evolving category that contains miscellaneous standards with different purposes, different strengths, and unclear influences relative to current medical practices, and is not easily unified into a single set of standards. On the other hand, courts will encounter great difficulty when attempting to use these guidelines to boost better medical practice because such radical interpretation of standard of care by courts is inconsistent with judicial passivity, and may have chilling effects on guideline creation, or at least can put impractical burdens on medical professionals.

However, courts cannot be indifferent to what is happening in the medical profession either. My suggestion is that, under certain qualifications, evidence-based guidelines can shed more light than expert testimony on standard of care, both on medical custom or reasonable physician standards.⁹¹ When a guideline is based on scientific evidence and expert consensus, it trumps individual experts in terms of accessibility and neutrality and is worthier of courts' trust than is expert testimony.⁹² Although guidelines will not replace individual experts because the application of guidelines to certain cases is still a process need professional judgment, yet it is desirable for both parties to use guidelines to

⁹¹ Because guidelines produced by different associations might have different recommendations, scholars worry that the introduction of guidelines as evidence in malpractice cases is just a shift from competing "individual" experts opinions to competing "super" experts. However, this paper thinks that guidelines provide information that is more objective than the information provided by experts, guidelines offer uniquely different levels of recommendations that juries or courts consult when forming judgments, and guidelines prompt defendant doctors to explain their actions or beliefs that deviate from the guidelines. This paper argues that guidelines' relatively objective information facilitates the truth finding in malpractice litigation.

⁹² Gilah R. Mayer, Bergman v. Chin: *Why an Elder Abuse Case Is a Stride in the Direction of Civil Culpability for Physicians Who Undertreat Patients Suffering from Terminal Pain*, 37 New England Law Review, 313, 344 (2003).

impugn or strengthen an individual expert's opinion, thus facilitating fact finding in courtrooms.⁹³ Nevertheless, courts should play a gate-keeping role in the admittance of guidelines with the following qualifications.

First of all, courts should be aware whether the guideline at issue represents current medical practice or an expectation for better practice.⁹⁴ Courts can look at the dissemination circumstances of guidelines by looking at empirical studies or consulting medical experts and administrators in healthcare institutions to determine. Second, courts should recognize the purposes of evidence-based guidelines, and should especially filter out the cost-oriented guidelines created by third-party payers. On the one hand, penalizing a doctor with malpractice liability for rendering a non-“cost efficient” decision might violate the proportionality principle and is inconsistent with the purpose of medical malpractice liability. On the other hand, physicians should not be able to cite their compliance with a cost-oriented guideline to justify negligence.⁹⁵ In contrast, the guidelines generated by professional associations or impartial third-party organizations are permissible because these guidelines tend to have a significant focus on patients’

⁹³ *Roper v. Blumenfeld*, 309 N.J. Super. 219, 706 A.2d 1151, 1156 (1998).

⁹⁴ Eddy, *supra* note 87. (Eddy is considered the father of clinical practice guidelines, and he proposed three different types of CPGs, standards, guidelines, and options, according to the different strength. Standards are expected to be followed strictly with rare exceptions, are commonly perceived as the golden rules of practice, and have acquired widespread recognition and compliance. Incompliance with standards might trigger accusations of negligence. Regarding guidelines, the expectation is that the medical community should follow them in most cases, but may deviate from them to fit individual cases. Doctors who are incompliant with guidelines should justify their incompliance. Options are the most flexible category of recommendations and make room for the judgments or preferences of each practitioner. See Mello, *supra* note 17, at 687-88.

⁹⁵ See Furrow, *Managed Care Organization and Patient Injury: Rethinking Liability*, 31 Georgia Law Review 419-519 (1997). (Torts liability has been imposed on third-party payers for denial of benefits on basis of utilization review.) However, in *Pegram v. Herdrich*, the U.S. Supreme court states in dicta that a doctor should not be constrained by financial interests (which place insufficient emphasis on the provision of care), and physicians’ duty to care for patients should act as a check to this financial influence. See *Pegram v. Herdrich*, 530 U.S. 211, 120 S.Ct. 2143 (U.S. 2000).

health and because doctors' compliance with these guidelines is closely correlated with what we expect from good medical practice.

Last but not least, Courts must keep in mind that it is powerful to use malpractice liability to implement guidelines and shape physicians' behaviors, but it also places a stranglehold on individual physicians' professional judgments. Moreover, courts should avoid allowing an evidence-based guideline, especially when it is different from accepted current practice, to directly influence standards of care without analyzing the possible consequence. Otherwise, a court will incur the risks of endowing an aspirational standard with the compelling legal power, and overstepping its passive judicial role to guarantee and to promote a single standard as a universal desirable medical practice, which is against the choice made by the medical profession as a whole to keep evidence-based guidelines as aspirational.